IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civ. No. 07-468-LPS
	:	
RYMED TECHNOLOGIES, INC.,	:	
	:	
Defendant.	:	
	:	

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MEMORANDUM OPINION

September 30, 2013
Wilmington, Delaware.

STARK, U.S. District Judge:

In this patent infringement action, the Court held jury trials in December 2010 and May 2012, as well as a bench trial in May 2012. Pending before the Court is the issue of the viability of the jury's verdicts of infringement under the doctrine of equivalents, in light of prosecution history estoppel. This dispute was the subject of the bench trial.

I. BACKGROUND

A. The Parties

Plaintiff ICU Medical, Inc. ("ICU") filed its complaint against Defendant RyMed Technologies, Inc. ("RyMed") on July 27, 2007, alleging infringement of United States Patent Nos. 5,865,866 (the "'866 patent"); 5,873,862 (the "'862 patent"); 5,928,204 (the "'204 patent"); and 6,572,592 (the "'592 patent") (collectively, "the patents-in-suit"), pursuant to 35 U.S.C. § 271. (D.I. 1) All of the patents-in-suit share a common specification.

B. The Pleadings

Rymed filed an answer and counterclaims on October 12, 2007 (D.I. 14), and ICU answered the counterclaims on November 1, 2007 (D.I. 20). Following other amendments, Rymed's second amended answer and counterclaims was deemed filed on December 16, 2009 (D.I. 359), and ICU responded to the amended counterclaims on January 11, 2010 (D.I. 379). In its second amended answer, Rymed raised various affirmative defenses, including prosecution history estoppel.

C. The Patents-In-Suit, ICU's Products, and Rymed's Accused Products

This case was previously assigned to the Honorable Joseph J. Farnan, Jr., now retired, who construed the disputed claim terms in December 2009. (D.I. 297) The patents-in-suit relate

to needleless intravenous medical connector valves. (D.I. 296 at 1) As noted by Judge Farnan in his claim construction opinion:

> Such valves are used to facilitate both the transmission of medication and fluids into a patient's bloodstream, as well as the withdrawal of a patient's blood. Before the patents-in-suit, the traditional technique for changing or adding fluid bags to an existing intravenous line required the insertion of an external needle into a needle access port, which was then connected to the existing intravenous line. Numerous problems existed with this traditional practice, for example, detachment of the needle, or contamination of the needle posed serious safety risks to patients, and accidental needle sticks posed the risk of infection to medical personnel.

(*Id.*)

ICU's products are known as the CLAVE and MicroCLAVE. Rymed's accused product is known as the InVision-Plus. ICU accuses of infringement both Rymed's original InVision-Plus as well as a modified version of the In-Vision-Plus with a helical boot.[1]

D. The Trials

1. December 2010 Jury Trial

Between December 13 and 17, 2010, the Court held a jury trial on the issues of infringement, validity, and willfulness. (*See* D.I. 516-520) ("Trial Tr. I") The December 2010 jury found that RyMed's original InVision-Plus product literally infringed the asserted claims of both the '866 and '862 patents; specifically, the original InVision-Plus product literally infringed

[1]Essentially, the difference between the original InVision-Plus and the modified InVision-Plus is that while the original version had a resilient seal with O-ring elements stacked on top of one another, the modified product has a resilient seal with O-ring elements (if at all) in a helical configuration. (*See generally* 10/3/11 Tr. (D.I. 525) As used in both the '866 and '862 patents, the Court construed "O-ring elements" to mean "portions having a circular outer surface that is wider at the middle than at the top or bottom." (D.I. 297)

claims 1, 3, and 6 of the '866 patent as well as claim 2 of the '862 patent. (D.I. 498, questions 1 & 5)

With respect to Rymed's "modified" InVision-Plus with a helical boot, the jury found literal infringement of dependent claims 3 and 6 of the '866 patent but no literal infringement of independent claim 1 of the '866 patent. (D.I. 498, question 2) The jury also found literal infringement of claim 2 of the '862 patent. (*Id.*, question 6) The jury found infringement under the doctrine of equivalents for each asserted claim; i.e., claims 1, 3, and 6 of the '866 patent as well as claim 2 of the '862 patent. (*Id.*, questions 3 & 7)

Following trial, the Court found that the jury's verdicts with respect to literal infringement of the '866 patent by the modified InVision-Plus were inconsistent, because the jury found no literal infringement of independent claim 1 but did find literal infringement of claims 3 and 6 – both of which depended from claim 1 and, necessarily, included all of the limitations of claim 1. (*See* Transcript of 9/16/11 hearing (D.I. 527) (hereinafter ("9/16/11 Tr.") at 50-51; D.I. 524) Accordingly, the Court granted ICU's motion for a new trial regarding literal infringement of claims 1, 3, and 6 of the '866 patent by the modified InVision-Plus product. (D.I. 524)

At the same time, the Court denied RyMed's motion for a new trial with respect to literal infringement of claim 2 of the '862 patent. (D.I. 524; *see also* 9/16/11 Tr. at 51-52) RyMed argued that the jury's finding of literal infringement of this claim could not be reconciled with the jury's finding that the modified InVision-Plus did not literally infringe claim 1 of the '866 patent. (*See* D.I. 506 at 10-11) The Court disagreed, finding that there was substantial evidence supporting the jury's finding of literal infringement of claim 2 of the '862 patent and that there was no inconsistency requiring a new trial on the '862 patent. (*See* D.I. 524; 9/16/11 Tr. at 52-

53)

2. May 2012 Jury Trial

Between May 7 and 9, 2012, the Court held a jury trial to consider literal infringement of claim 1 of the '866 patent by the modified InVision-Plus product. (*See* D.I. 563-565) ("Trial Tr. II") As the Court instructed the jury, "the only disputed [factual] issue [was] whether RyMed's accused InVision-Plus product contains a 'seal comprising a series of O-ring elements stacked together to form a unitary structure.'" (D.I. 559; *see also* D.I. 563, Trial Tr. II at 18; D.I. 565, Trial Tr. II at 506) The jury found that Rymed's modified InVision-Plus did not literally infringe claim 1 of the '866 patent. (D.I. 557; D.I. 558)

3. May 2012 Bench Trial

On May 11, 2012, the Court held a bench trial to consider RyMed's prosecution history estoppel defense, by which RyMed seeks to set aside the December 2010 jury verdicts of infringement under the doctrine of equivalents of both the '866 and '862 patents. (*See* D.I. 569) ("Bench Trial Tr.") ICU stipulated that, due to amendments made to the claims during prosecution of the '866 and '862 patents, "[t]here is a presumption of prosecution history estoppel as to the alleged equivalents in claims 1, 3, and 6 of the '866 patent and claim 2 of the '862 patent." (D.I. 535 at 12, stipulation 1; *see also* Bench Trial Tr. at 519, 523-24) ICU seeks to rebut the presumption of prosecution history estoppel on the grounds that the reasons for the amendments were only "tangentially" related to the equivalent in question. (D.I. 535 at 12, stipulation 2; Bench Trial Tr. at 519) Such "tangentiality," if proven, is a settled exception to prosecution history estoppel. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002) ("*Festo VIII*") ("Nor is there any call to foreclose claims of equivalence for

aspects of the invention that have only a peripheral relation to the reason the amendment was submitted."); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1366–67, 1374 (Fed. Cir. 2003) ("*Festo IX*").

At trial, the Court heard testimony from each side's expert, primarily as to what one of ordinary skill in the art would find to have been disclosed in several prior art references. (Bench Trial Tr. at 522, 524-25) ICU presented the testimony of Mr. Claude Vidal, a mechanical engineer and expert in medical device design. (Trial Tr. II at 209; Bench Trial Tr. at 530-67) RyMed presented the testimony of Mr. Karl Leinsing, a mechanical engineer and expert in medical devices, including intravenous needlefree connectors and needlefree valve designs. (Bench Trial Tr. at 567-600) Among the evidence introduced by the parties are the file histories for the '866 and '862 patents, including the patents themselves. (*See* JX1, '866 patent; JX3, '866 patent file history; JX4, '862 patent; JX5, '862 patent file history)[2]

II. DISCUSSION

A. Legal Standards

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements

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[2]ICU contends that the only prior art relevant to the Court's decision is that which was cited by the Examiner in the rejections that led to the amendments at issue. At trial, RyMed took a slightly broader position, offering evidence of two other patents that were cited on the face of the '866 and '862 patents: Armao '380 (DX-7) and Haining '245 (DX-13). (*See* Bench Trial Tr. at 525, 584, 586, 593) When ICU objected to admission of the additional prior art, the Court instructed, "if you want to maintain that objection, it will be the subject of post-trial briefing." (*Id.* at 525; *see also id.* at 601) As ICU did not press its objections in its post-trial briefs, the previously challenged exhibits, DX-7 and DX-13, are admitted.

of the patented invention." *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). "When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim [during prosecution] in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo VIII*, 535 U.S. at 733–34.

There is "a presumption that a narrowing amendment made for a reason of patentability surrenders the entire territory between the original claim limitation and the amended claim limitation." *Festo IX*, 344 F.3d at 1365. In such a situation, the Court must presume that the patentee is precluded from using the doctrine of equivalents to prove infringement. *See id.* at 1367. In order to rebut this presumption, "the patentee must demonstrate that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment, that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or that there was some other reason suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent." *Id.* at 1368 (internal quotation marks omitted). "[I]f the patentee fails to rebut the *Festo* presumption, then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for the accused element." *Id.* at 1367.

Prosecution history estoppel is a matter for the Court to decide. *See Warner–Jenkinson*, 520 U.S. at 39 n.8; *see also Festo IX*, 344 F.3d at 1367-68 ("[W]hether prosecution history estoppel applies, and hence whether the doctrine of equivalents may be available for a particular claim limitation, presents a question of law."). With respect to the "tangentiality" exception, the Court must "focus[] on the patentee's objectively apparent reason for the narrowing amendment"

in the "context in which the amendment was made." *Festo IX*, 344 F.3d at 1369-70. Tangentiality is demonstrated when "the reason for the narrowing amendment was peripheral, or not directly relevant" to the equivalent in question. *Id.* at 1369. Further, "that reason [for the amendment] should be discernible from the prosecution history record, if the public notice function of a patent and its prosecution history is to have significance." *Id.* "If the prosecution history reveals no reason for the narrowing amendment, the presumption is not rebutted. . . . Silence does not overcome the presumption." *Honeywell Int'l v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315-16 (Fed. Cir. 2008) (internal citation omitted). Importantly, the Federal Circuit has stated that "the tangential relation criterion for overcoming the *Festo* presumption is very narrow." *Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007).

The issue before the Court is whether ICU can overcome the presumption of prosecution history estoppel that would otherwise preclude its contention that RyMed's modified InVision-Plus product with a helical boot infringed the asserted claims of the '866 and '862 patents under the doctrine of equivalents. The parties agree that the presumption of prosecution history estoppel applies, and further agree that ICU has an opportunity to attempt to rebut that presumption by showing that the rationale for the amendment bore no more than a tangential relation to the equivalent in question. Before addressing the parties' disputes with respect to the '866 and '862 patents, the Court will first describe the pertinent prosecution histories.

B. Prosecution History

1. '866 Patent

The pertinent prosecution history of the '866 patent is in the trial record. (*See* JX3; *see*

also D.I. 566 App. A) ICU filed the patent application that became the '866 patent on November 4, 1994. After independent claim 1 was rejected on October 19, 1995, on April 24, 1996 ICU amended claim 1 and added claims including dependent claim 67 – which eventually became claim 1 of the '866 patent. Specifically, amended claim 1 of the application read:

> 1. (Amended) A medical valve comprising:
>
> a body including wall structure defining an internal cavity having a proximal end and a distal end,
>
> said proximal end having an opening sufficiently large to receive a delivery end of a medical implement which transfers fluid through said delivery end;
>
> a spike having a tip, at least one hole located at or near said tip, and a passageway in communication with the hole that allows fluid to flow through said hole,
>
> said spike being seated within the cavity such that said tip is enclosed within the cavity; and
>
> a resilient seal which is adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement into said opening, said seal moving proximally in the cavity and returning to a decompressed state upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent said opening, said seal section bearing against said wall structure near said opening to seal said opening, and in the compressed state said seal section being located in the cavity distal of said opening.

(JX3 at 95-96) Dependent claim 67 of the application read:

> The medical valve of claim 1, wherein said seal ***comprises a series of O-ring elements stacked together and connected to form a unitary structure***.

(JX3 at 97) (emphasis added)

On December 17, 1996, the Examiner rejected application claim 1 as anticipated by a prior art reference, U.S. Patent No. 5,273,533 ("Bonaldo '533" (JX6)). (JX3 at 110; *see also* Bench Trial Tr. at 531-33, 549) In particular, the Examiner noted that "the embodiment of figures 5 and 6 [of Bonaldo 533] . . . reads on the structure of the device as claimed" in application claim 1. (JX3 at 110) At trial, both parties' experts agreed that this embodiment of Bonaldo 533 has a straight-walled seal and contains no O-ring elements. (Bench Trial Tr. at 531-33, 595) In the same December 17, 1996 office action, the Examiner further objected to claims including claim 67 "as being dependent upon a rejected base claim," but added these claims "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." (JX3 at 111)

Thereafter, on March 17, 1997, ICU submitted amended claim 67 in independent form, just as the Examiner had suggested. In connection with its submission, ICU stated to the PTO:

> By this response, Applicant has canceled Claims 1, 60-66, 71 and 72 without prejudice, and has rewritten Claims 67 and 69 into independent form. Applicant has added new Claims 73-78 dependent upon Claim 67, and Claims 79-85 dependent upon Claim 69. Applicant believes that independent Claims 67 and 69 (as amended) are now in condition for allowance, as are Claims 68, 70 and 73-85 dependent thereon.

(JX3 at 117) With no additional comment from ICU relating to the amendment, and none from the Examiner, on April 22, 1997 the PTO issued a Notice of Allowability. (JX3 at 120) The '866 patent issued on November 11, 1997, with prosecution claim 67 issuing as independent claim 1. (JX1)

Claim 1 of the '866 patent reads:

> 1. A medical valve comprising:

> a body including wall structure defining an internal cavity having a proximal end and a distal end, said proximal end having an opening sufficiently large to receive a delivery end of a medical implement which transfers fluid through said delivery end;
>
> a spike having a tip, at least one hole located at or near said tip, and a passageway in communication with the hole that allows fluid to flow through said hole, said spike being seated within the cavity such that said tip is enclosed within the cavity; and
>
> a resilient seal which is adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement into said opening, said seal moving proximally in the cavity and returning to a decompressed state upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent said opening, said seal section bearing against said wall structure near said opening to seal said opening, and in the compressed state said seal section being located in the cavity distal of said opening, said seal comprising a ***series of O-ring elements stacked together and connected to form a unitary structure***.

(JX1) (emphasis added)

2. '862 patent

The pertinent prosecution history of the '862 patent is in the trial record. (*See* JX5; *see also* D.I. 566 App. B) ICU filed the patent application that became the '862 patent on April 22, 1997. (JX5 at 6-7) It included independent claim 60, which read:

> 60. A method of transferring fluid from a remote source to a patient, comprising:
>
> (a) connecting a medical valve to the patient, wherein the valve comprises a body including wall structure defining an internal cavity having a proximal end and a distal end, said proximal end having an opening sufficiently large to receive a delivery end of a medical implement which transfers fluid through said delivery end, a spike having a tip, at least one hole located at or near said tip, and a passageway in communication with the hole that allows fluid to

> flow through said hole, said spike being seated inside the cavity such that said tip is enclosed within the cavity, and a resilient seal which is adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement into said opening, said seal moving proximally in the cavity and returning to a decompressed state upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent said opening, said seal section bearing against said wall structure near said opening to seal said opening, and in the compressed state said seal section being located in the cavity distal said opening, wherein said seal has a groove to facilitate the movement of the seal;
>
> (b) inserting the delivery end of the medical implement into said opening; and
>
> (c) pushing said delivery end into the cavity to compress said seal sufficiently to allow fluid to flow from said medical implement through said valve to the patient.

(*Id.* at 65-67) The application also included dependent claim 70 – which eventually became claim 2 of the '862 patent – which read:

> 70. The method of Claim 60, ***wherein said groove is defined by at least two O-ring elements***.

(*Id.* at 67) (emphasis added)

On November 13, 1997, the Examiner rejected claim 60 as anticipated by prior art references U.S. Patent No. 3,986,508 ("Barrington '508") (JX7) and U.S. Patent No. 5,154,703 ("Bonaldo '703") (JX8). (*See* Bench Trial Tr. at 531-35, 549, 574-75; JX5 at 97-98) The Examiner also rejected dependent claim 70 as indefinite under 35 U.S.C. § 112, stating "it is not clear if the 'at least two O-ring elements' are on the seal or make up the seal." (JX5 at 78) The Examiner added, "Claims 70 and 71 would be allowable if rewritten to overcome the rejection(s)

under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims." (*Id.* at 80)

On March 13, 1998, ICU responded by amending claim 70 to read: "The method of Claim 60, wherein said groove is defined by at least two O-ring elements forming a portion of said seal." (*Id.* at 86) ICU clarified that it "amended Claim 70 to specify that the at least two O-ring elements form a portion of the seal," and further stated that "[s]upport for amended Claim 70 can be found on page 15, line[s] 27-29, which disclose that the 'seal wall' consists 'of a plurality of ringed wall portions 94 that expand and collapse in an accordion like fashion.'" (*Id.* at 88) Then, on May 1, 1998, the PTO again rejected claim 60, this time for being obvious in light of Bonaldo '703 (JX8) and U.S. Patent No. 4,334,551 ("Pfister '551") (JX9), or Barrington '508 (JX7) and Pfister '551 (JX9). (*See* JX5 at 97-98) The Examiner also stated: "Claims 69-74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." (*Id.* at 98)

In its response on June 9, 1998, ICU cancelled claims 60-78 and added claims 79-83, stating: "New independent claims 79, 80 and 82 correspond to original Claims 69, 70 and 72 rewritten into independent form, and for this reason these claims are believed allowable." (*Id.* at 105, 109) With no additional comment from ICU relating to the amendment, and none from the Examiner, on August 18, 1998, the PTO issued a Notice of Allowability. (*Id.* at 111) The '862 patent issued on February 23, 1999, with claim 80 becoming independent claim 2. (*See id.* at 106-107; JX4)

Claim 2 of the '862 patent reads:

> 1. A method of transferring fluid from a remote source to a patient, comprising:
>
> (a) connecting a medical valve to the patient, wherein the valve comprises a body including wall structure defining an internal cavity having a proximal end and a distal end, said proximal end having an opening sufficiently large to receive a delivery end of a medical implement which transfers fluid through said delivery end, a spike having a tip, at least one hole located at or near said tip, and a passageway in communication with the hole that allows fluid to flow through said hole, said spike being seated inside the cavity such that said tip is enclosed within the cavity, and a resilient seal having a proximal end and a distal end and adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement into said opening, said seal moving proximally in the cavity and returning to a decompressed state upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent said opening, said seal section bearing against said wall structure near said opening to seal said opening, and in the compressed state said seal section being located in the cavity distal said opening, said seal being preslit at the proximal end thereof, ***wherein said seal has at least one groove defined by at least two O-ring elements*** forming a portion of said seal to facilitate the movement of the seal;
>
> (b) inserting the delivery end of the medical implement into said opening; and
>
> (c) pushing said delivery end into the cavity to compress said seal sufficiently to allow fluid to flow from said medical implement through said valve to the patient.

(JX4) (emphasis added)

C. ICU Has Not Met Its Burden

1. '866 patent

For the following reasons, the Court concludes that ICU has not met its burden of establishing that the amendment to claim 1 of the '866 patent "bore no more than a tangential

relation to the equivalent in question."

First, while the prosecution history reveals why ICU amended the claims to add the existence of O-ring elements, no "objectively apparent reason" is "discernable from the prosecution record" as to why ICU further amended the claims to add the "stacked together and connected to form a unitary structure" limitations. These "configuration" limitations narrowed the claims further than they would have been narrowed had ICU merely amended the claims to add just the limitation requiring the existence of O-ring elements.

RyMed correctly points out that "the amendment was a unitary whole, and the presence of O-ring elements and their configuration was never separately addressed in the prosecution history by ICU or the examiner." (D.I. 566 at 2) Indeed, as RyMed continues, "both the existence and configuration of the O-ring elements . . . were found in the same sentence, added at the same time, and related to the same part of the claimed invention." (*Id.* at 9) The prosecution history is silent as to why ICU followed the Examiner's recommendation and added the configuration limitations and not just the O-ring elements limitation that ICU believed was necessary to overcome the prior art rejection. Simply following the Examiner's unexplained suggestion, without any explanation from ICU, does not, on this prosecution history, suffice to satisfy the tangentiality exception. *See Honeywell*, 523 F.3d at 1316 (affirming conclusion of failure to rebut estoppel presumption where "record shows that the examiner simply instructed that the dependent claims would be allowed if rewritten into independent form").

ICU places great emphasis on the fact that "during the May 2012 [jury] trial, RyMed vigorously contended that 'series' and 'stacked together and connected' constituted limitations separate from the 'O-ring elements' limitation," reminding the Court that RyMed used a

demonstrative exhibit breaking down this portion of claim one into four components. (D.I. 561 at 11) (citing RyMed Demonstrative Ex. 1) RyMed's trial tactics, however, cannot establish the tangentiality of ICU's amendment. The issue of prosecution history estoppel must be resolved on the basis of the public record of the prosecution history made by the applicant and the PTO before issuance of the patent, not based on how an accused infringer years later may have attempted to simplify claim language for a jury.

RyMed relies on *Festo* and *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296 (Fed Cir. 2005), for the proposition that whether all of an amendment's claim language was "necessary" is "legally irrelevant" to the prosecution history estoppel inquiry. (D.I. 566 at 12-13) While the Court believes RyMed overstates the holdings of these cases, the Court agrees with RyMed to this extent: if portions of an amendment were not necessary for patentability, and the prosecution history reveals no other reason for those portions of the amendment, then the patentee has failed to show tangentiality. *See generally Energy Transp. Group, Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1360 (Fed. Cir. 2012) ("Prosecution history estoppel bars application of the doctrine of equivalents even where the applicant surrendered more claim scope than was necessary to overcome a rejection."). As the Federal Circuit stated in *Biagro*, while describing *Festo IX*, "The prosecution history revealed no reason for the amendment, and therefore Festo could not show that the rationale underlying the amendment was only tangential to the accused nonmagnetizable equivalent." 423 F.3d at 1306 (citing 344 F.3d at 1371-72). Likewise, in *Biagro* itself, the Federal Circuit held, "since the prosecution history shows no reason for adding an upper limit to the concentration range," a limit the patentee contended was not necessary to distinguish over prior art, the patentee "cannot claim that the rationale for the

amendment is merely tangential." 423 F.3d at 1306. Applying this principle here, it follows that: (i) even if ICU is correct that the configuration limitations were not necessary to distinguish over the prior art, (ii) the prosecution history reveals no reason – other than following, without explanation, an unexplained recommendation of the Examiner – for amending the claim with the configuration limitations, so (iii) ICU has failed to establish that the configuration limitations were tangential and it has not rebutted the presumption of prosecution history estoppel.

The second reason for the Court's conclusion that ICU has failed to meet its burden is that the Court is unable to conclude, on the record before it, that the PTO necessarily would have allowed an amended claim 1 that included only the existence of O-ring elements but contained no limitations as to the configuration of the O-ring elements. ICU's interpretation of the prior art and the reasoning for the Examiner's rejection – the presence of straight-walled seals in Bonaldo '533 – is persuasive, but not dispositive. Because there is no discussion by either the Examiner or ICU of the reason for the addition of the configuration limitations, the Court is not sure what the Examiner would have done with an amended claim that did not include the configuration limitations.

It is true, as ICU emphasizes, that in connection with prosecution of the related '862 patent, the same Examiner who participated in the PTO's consideration of the '866 patent allowed claim 2 – after an amendment which followed a prior art rejection – based on the addition of a limitation of just the existence of O-ring elements, with no reference to the configuration of the O-ring elements. (*See* D.I. 561 at 15-16) While this is some indication that this Examiner would also have allowed claim 1 of the '866 patent with just the addition of O-ring

elements, it, too, is not dispositive.[3] The '866 and '862 patents are (necessarily) different patents, encompassing different inventions; in particular, the '862 patent requires a "groove" that is not present in the asserted claims of the '866 patent. *See generally Kearns v. General Motors Corp.*, 94 F.3d 1553, 1556-57 (Fed. Cir. 1996) ("[E]ach patent, by law, covers a[n] independent and distinct invention . . . ."). The Court agrees with RyMed that "[j]ust because the PTO found that the combination of that 'groove' with O-ring elements made '862 claim 2 patentable does not mean that in a separate prosecution (claim 1 of the '866 patent) the PTO would have found the existence of O-ring elements without such a groove allowable." (D.I. 566 at 2-3)

Third, ICU has failed to demonstrate that "the equivalent" in the RyMed modified InVision-Plus is the configuration of the O-ring elements, as opposed to the existence of the O-ring elements. (*See id.* at 20) (RyMed arguing: "Even if ICU could show that the reason for the amendment was only the O-ring elements themselves and not their configuration," ICU's "tangential relation argument fails because the RyMed helical boot was claimed to be the equivalent of the O-ring elements, not solely their configuration") That is, the Court is not persuaded by ICU's assertion that the element which the December 2010 jury "must have found" by equivalence is, and only is, the configuration of the O-ring elements. Instead, the Court agrees with RyMed: "It is improper to determine what the jury must have found on the doctrine of equivalents on claim 1 of the '866 patent based on a verdict on literal infringement of claim 2 of the '862 patent." (*Id.* at 3) Because the Court cannot rule out the possibility that the jury found

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[3]In its reply brief, ICU implicitly acknowledges that, at best, the '862 prosecution history merely "***helps*** demonstrate that the Examiner ***probably would have*** allowed claim 1 of the '866 patent even if the configuration limitations had not been included." (D.I. 567 at 9) (emphasis added)

the presence of O-ring elements for purposes of the '866 patent only under the doctrine of equivalents – and even ICU acknowledges it "is estopped from reaching equivalents of O-ring elements" (D.I. 561 at 14-15) – the Court concludes, again, that ICU has failed to meet its burden.

ICU contends that reading the equivalents in question as including the existence of O-ring elements, and not just their configuration, "invites inconsistency among the verdicts, which is improper and unnecessary." (D.I. 567 at 2; *see also* D.I. 561 at 14 (ICU contending, "[i]n returning a verdict of literal infringement of claim 2 of the '862 patent, the 2010 jury necessarily found that O-ring elements are literally present in the InVision-Plus product")) The Court disagrees. ICU overstates the authority on which it relies for the proposition that "[a] court has an obligation to attempt to read the verdicts in a manner that will resolve the inconsistencies." (D.I. 567 at 2) (citing *Mosley v. Wilson*, 102 F.3d 85, 90-91 (3d Cir. 1996); *Kinnel v. Mid-Atlantic Mausoleums, Inc.*, 850 F.2d 958, 965 (3d Cir. 1988)). Anyway, here, in December 2010, there were inconsistent verdicts: the jury found no literal infringement of independent claim 1 of the 866 patent yet literal infringement of dependent claims 3 and 6. (*See* D.I. 527 at 50) In addition, two juries (in December 2010 and May 2012) have found ***no literal infringement*** of claim 1 of the '866 patent – verdicts that are consistent with one another, and which indicate that two juries did not find O-rings literally present when evaluating the modified InVision-Plus in the context of the '866 patent's claim 1. While the Court does not know why the December 2010 jury reached the conclusions it did with respect to the '866 and '862 patents – and ICU is certainly correct that the Court construed O-ring elements identically for purposes of the '866 and '862 patents – the Court also finds no basis in that uncertainty for importing the '862

conclusion into the '866 claims, particularly when two separate juries expressly declined to find that the '866 O-ring elements limitation was literally met.[4]

"This Court requires a strong showing . . . to satisfy the 'very narrow' exception to prosecution history estoppel for amendments only tangentially related to the equivalent in question." *Energy Transp. Group, Inc.*, 697 F.3d at 1359. Having reviewed the evidence of record and considered the arguments of the parties, the Court concludes that ICU has failed to make the required strong showing. Accordingly, RyMed is entitled to judgment of non-infringement under the doctrine of equivalents of claims 1, 3, and 6 of the '866 patent.

2. '862 Patent

The parties devote only a small portion of their post-trial briefing to the issue of whether ICU has rebutted the presumption of prosecution history estoppel in connection with claim 2 of the '862 patent. (*See* D.I. 561 at 15-17; D.I. 566 at 25; D.I. 567 at 9) The Court will follow their example.

Here, ICU has a stronger argument that there is an objectively discernable reason for the amendment, an amendment which added the O-ring elements but no additional limitations

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[4]In the context of ruling on a motion in limine, the Court stated, "it's likely that the [December 2010] jury found that the O-ring elements exist in the modified product." (*See* PTC Tr. Apr. 10, 2012 (D.I. 545) at 44-45) Plainly, saying "it's likely" was not a holding that the December 2010 jury did make, or must have made, such a finding. Indeed, the Court rejected ICU's contention that claim preclusion should apply because the Court concluded that the infringement issues presented in connection with the '862 patent were not the same as the infringement issues presented in connection with the '866 patent. (*See id.*) Moreover, the Court has repeatedly emphasized that it instructed the December 2010 jury to consider each of the patents separately, and neither party proposed that the Court do otherwise. (*See, e.g.*, D.I. 492 at 22; D.I. 545 at 44) Additionally, as ICU observed in connection with briefing post-trial motions: "Neither party ever suggested a jury instruction indicating the infringement verdicts had to relate to each other in any particular way." (D.I. 566 at 23 n.3)

relating to their configuration. The O-ring elements were not present in the prior art on which the Examiner based its rejection; the Examiner suggested that if the claim was rewritten in independent form including the O-ring elements it would be allowed; and ICU amended the claims according to the Examiner's suggestion, without adding other limitations that narrowed the claims any further.

The problem for ICU, and where it has failed to meet its burden, is that the Court is uncertain whether the "equivalent in question" is the O-ring elements. As RyMed explains, the evidence presented by ICU relating to infringement by equivalence in the context of the '862 patent related to the O-ring elements. (*See* D.I. 566 at 7) (citing Trial Tr. at 533) Because the finding of infringement of equivalence may have been predicated on a finding of the presence of O-ring elements only by equivalence, yet the existence of O-ring elements was not tangential to the claim amendment, the Court concludes that ICU has failed to meet its burden. Accordingly, judgment will be entered for RyMed on infringement of claim 2 of the '862 patent under the doctrine of equivalents.

IV. CONCLUSION

ICU has not overcome the presumption of prosecution history estoppel. Accordingly, the Court will enter judgment for RyMed on ICU's claim of infringement under the doctrine of equivalents of claims 1, 3, and 6 of the '866 patent and claim 2 of the '862 patent. An appropriate Order follows.